Connecting Patients With Specialty Products

Part 1: Distribution models for biologics and other specialty pharmaceutical products

In this first of a two-part series, we examine the distribution landscape for specialty pharmaceuticals. A manufacturer's strategy for the flow of product to patient has important implications for payers and for the success of a new biologic therapy.

BY JACK McCAIN

If payers and patients can figure out how to pay for them, specialty pharmaceuticals appear to be the future of pharmacy. Express Scripts has estimated that by 2014, specialty products will account for 40 percent of total drug spending (medical and pharmacy benefits) in the United States (Nease 2011). Carrying the promise of targeted treatments for patients and substantial rewards for drug manufacturers, specialty pharmaceuticals have captured the drug industry's attention in a big way. "Pharmaceutical companies are in hot pursuit of specialty products through their own R&D as well as looking to purchase," says Ron Krawczyk, a managing partner of Chesterfield, Mo.-based Blue Fin Group, a life-sciences management and technology consultancy. "Competition is fierce and prices are high."

Krawczyk and other industry observers say that drug manufacturers and payers have not yet grasped the complexities of the distribution channels through which specialty products flow from manufacturer to patient. Drug companies are interested in profiting from the efficient movement of products to patients. Payers tend to be interested in the channels that offer these products at the lowest price — and these interests are not necessarily aligned.

"Despite high spending, the distribution of specialty pharmaceuticals remains a very immature marketplace," says Krawczyk. It's not just the flow of products to patients that's critical, he says, but also the various financial and transactional flows as well.

"Every specialty pharmaceutical product should have its own go-to-market strategy," says Adam Fein, PhD, president of Philadelphia-based Pembroke Consulting, which specializes in drug distribution channels. "The variety of services, prices, contracting, and reimbursement is infinite. Manufacturers are the channel captain, but payers can influence them by designating their own preferences."

Finding the right distribution model

Sometimes, the distribution strategy a drug manufacturer selects for a new specialty product is just the same old strategy it has used to launch its traditional pharmaceuticals. Krawczyk cautions, however, that this simple approach may not work — manufacturers who ignore the many factors that affect distribution channels (Figure 1) do so at their own peril.

Failure to construct a good distribution channel for a new specialty pharmaceutical product can result in poor prescriber uptake. For example, if a drug manufacturer launches an injectable product through a channel that precludes buy and bill, some physicians may decide not to bother with it — especially if treatment alternatives are available.

Often, however, prescribers and payers have no choice because many specialty pharmaceuticals are one-of-a-kind products developed for small patient populations. For example, ipilimumab (Yervoy), in theory, could be prescribed for a maximum of only about 8,000 U.S. patients with metastatic melanoma each year. Even fewer patients with metastatic melanoma would qualify for another new specialty product, vemurafenib (Zelboraf), because it is effective only in the subset of patients whose tumors carry a certain mutation.

"Manufacturers are looking for biologics to solve a particular problem," says Elan Rubinstein, PharmD, MPH, principal at EB Rubinstein Associates, in Oak Park, Calif. For many drugs, health plans can establish formularies that designate preferred and nonpreferred products, but Rubenstein points out that such a strategy won't work in therapeutic areas where there is little or no product choice.

Specialty pharmacies typically enter a distribution model for drugs covered under the pharmacy benefit. To mitigate payers' cost fears, specialty pharmacies emphasize programs that promote adherence to therapy and reduce waste. For ex-

ample, says Rubinstein, they might package oral specialty products in a manner that helps patients remember to take them. Or, if records show that a patient hasn't requested a necessary refill, the specialty pharmacy will call the patient as a reminder.

The challenge that specialty pharmacies face is demonstrating that these services add value.

"Employers know that increasing adherence to diabetes drugs leads to better outcomes, but they do not know that the same holds true for many specialty drugs," says Rubinstein. "They know that better adherence means their costs for specialty drugs will increase. But are their medical costs going down as a consequence of the increased adherence? Is the productivity of their employees going up?"

Affirmative answers to these questions could strengthen the role of specialty pharmacies in distribution models. Negative answers could signal further changes in the industry as players seek the right models.

Medical vs. pharmacy benefit

Contemporary channels for specialty products can be grouped into two general forms reflecting whether a product is financed under the pharmacy benefit (Figure 2, page 10) or the medical benefit (Figure 3, page 11). Fein says that about half of specialty pharmaceuticals are covered under the medical benefit and half under the pharmacy benefit.

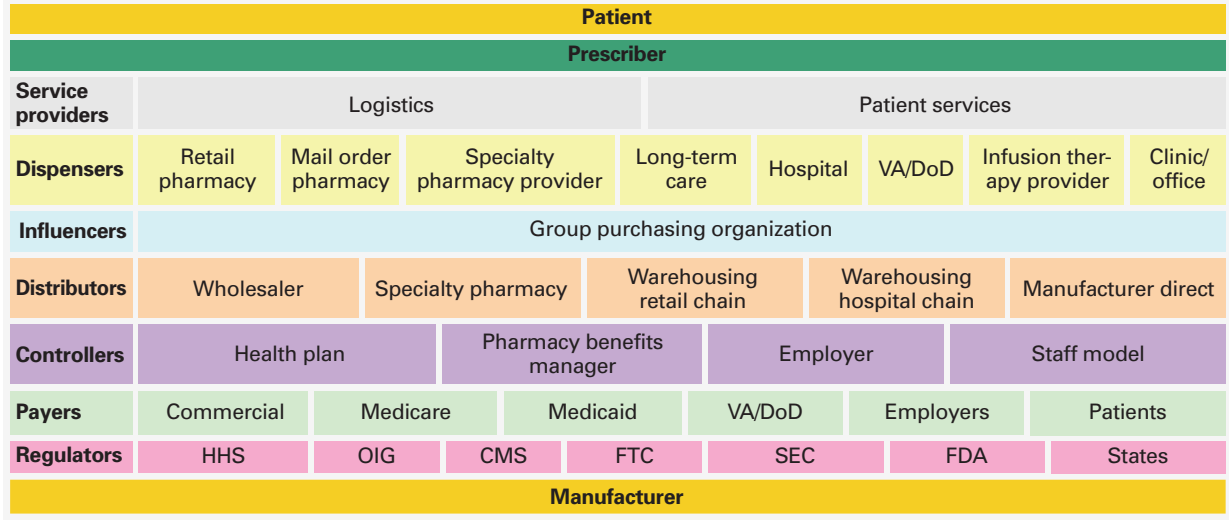
Placing a specialty drug under the pharmacy benefit often provides the opportunity for tighter control in real time. According to Rubinstein, pharmacy benefit managers (PBMs) are trying aggressively to move drugs from the medical to the pharmacy side, or, in some cases, leaving them on the medical side but applying a pharmacy-benefit type of administration. If successful, Rubinstein says, this strategy will garner new drug volume for the PBMs and improve payers' ability to track utilization.

Some specialty pharmacies are large enough to acquire products directly from the drug manufacturer. Small specialty pharmacies and retail pharmacies that handle specialty pharmaceuticals use the services of a specialty wholesaler (sometimes called specialty distributors). The largest specialty pharmacies are owned by PBMs or large retailers. Whether large or small, specialty pharmacies seek to carve out a niche by offering services that are beyond the capabilities of the typical retail pharmacist, from storage of products to education of patients with rare diseases.

Hubs and restricted channels

Manufacturers often employ reimbursement hubs to facilitate use of

FIGURE 1
The prescriber-payer matrix

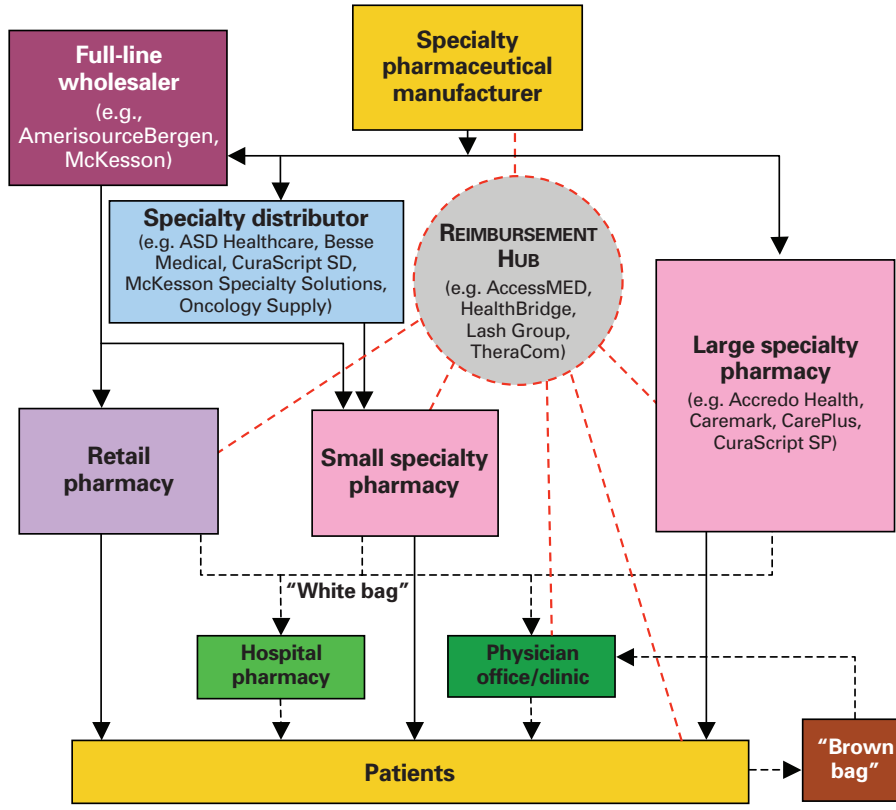


This figure depicts the many physical, financial, and transactional factors that manufacturers of specialty pharmaceuticals must take into consideration when they devise channels through which products will reach patients. Though manufacturers are in control of their channels, payers can influence them.

CMS=Center for Medicare & Medicaid Services, DoD=Department of Defense, FDA=U.S. Food and Drug Administration, FTC=Federal Trade Commission, HHS=Department of Health and Human Services, OIG=Office of the Inspector General, SEC=Securities and Exchange Commission, VA=Department of Veterans Affairs.

Source: Blue Fin Group 2012

FIGURE 2
Channels leading to dispensing of specialty products under the pharmacy benefit



Solid arrows connect links in the chains through which specialty products flow from manufacturer to patient, with a dispensing pharmacist being the penultimate link. *Dashed black arrows* indicate "white bagging" and "brown bagging" dispensing strategies that eliminate the buy-and-bill process, through which healthcare providers are reimbursed for their drug purchases under the medical benefit. Except for the office-administered products delivered via white- or brown-bagging, all the other specialty products flowing through these channels are administered by the patient or a caregiver. *Dashed red lines* indicate connections between reimbursement hubs, prescribers, and pharmacies. Hired and funded by manufacturers, hubs provide numerous services for providers, payers, and patients.

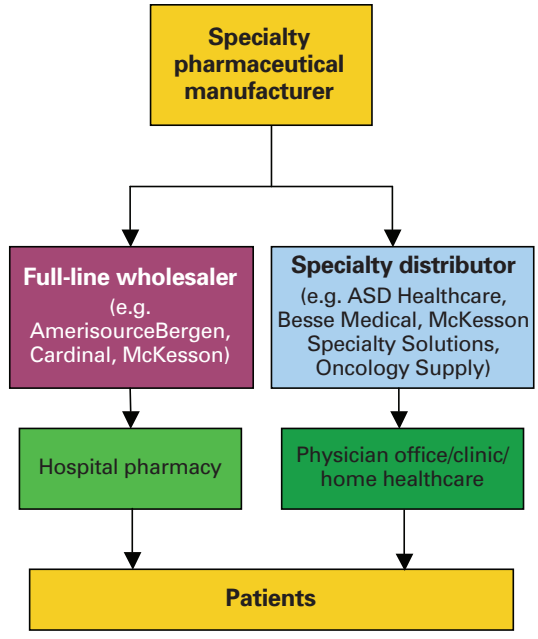
Source: Pembroke Consulting 2012

their products. Hubs provide numerous services for providers, payers, and patients. For example, hubs typically have toll-free numbers that physician offices can call for reimbursement assistance, thereby reducing administrative overhead at the office. Hubs also offer copayment and patient-assistance services, programs to promote adherence to therapy, and HIPAA-compliant data collection and reporting services. For Krawczyk, hubs provide three critical services: attracting patients to therapy, initiating therapy, and retaining patients on therapy.

In theory, any licensed pharmacy can dispense any pharmaceutical product. In practice, manufacturers often find it advantageous to restrict channels for their specialty drugs. One reason is to maintain product integrity. For example, Genentech has authorized only four specialty distributors — BioSolutions Direct, Besse Medical/Oncology Supply, CuraScript Specialty Distribution, and McKesson Specialty Solutions — to provide bevacizumab (Avastin) to physician offices. Hospitals and federal accounts can acquire bevacizumab through only five full-line wholesalers — AmerisourceBergen, Cardinal Health, HD Smith, McKesson, and Morris & Dickson. Genentech says these specialty distributors and wholesalers have agreed not to distribute bevacizumab through secondary wholesalers.

Recently, 19 oncologists tried to bypass this safeguard. They purchased what they thought was bevacizumab from a vendor not among the four authorized distributors, presumably because they could buy it at a better price. Instead, they ended up with a counterfeit product concocted somewhere in the Middle

FIGURE 3
Channels leading to administration of specialty pharmaceuticals under the medical benefit



When specialty pharmaceuticals reach patients through these channels, claims are usually reimbursed through the medical benefit. Physician offices and clinics are served by specialty distributors, which are often subsidiaries of full-line wholesalers, such as AmerisourceBergen or McKesson. The four subsidiaries cited as examples of specialty distributors have a 75% share of specialty distribution.

Source: Pembroke Consulting 2012

East — it contained no bevacizumab whatsoever (FDA 2012). Constructing restricted-access channels is a good way for manufacturers to fight counterfeiters, says Fein.

Rubinstein points to additional benefits from restricted channels: controlling the drug flow; limiting the amount of drug in the channel where products are costly or in short supply; collecting distribution data; and collecting patient-use data, which is sometimes required by the FDA.

It's in the bag

White bagging and its cousin, *brown bagging*, are side channels sometimes employed to circumvent the buy-and-bill process. In white bagging, the specialty pharmacy ships the product directly to the site of care just in time for the patient's scheduled treatment. In brown bagging, the specialty pharmacy dispenses the product directly to the patient, who assumes responsibility for its safe storage and transport to the site of care.

In the case of high-priced specialty drugs, some physicians are content with white bagging because they'd rather let someone else buy the drugs, especially if there's a chance that reimbursement will be delayed or even denied. It also protects providers from absorbing the cost of an expensive product if a patient does not show up for an appointment or if the drug is lost to circumstances beyond their control (providers on the east coast, for instance, reported spoilage of costly specialty drugs under refrigeration last summer when Hurricane Irene caused days-long power outages).

On the other hand, white bagging eliminates physicians as middlemen, thus denying them the markup they would have received under buy-and-bill. It also makes some office practices unhappy because it requires them to store and keep track of the product without being paid a fee for doing so.

Brown bagging relieves the provider of inventory control and storage responsibilities but increases the risk of product wastage due to improper storage. For safety reasons, some healthcare providers refuse to administer specialty pharmaceuticals brought to the office by the patient.

Consolidation

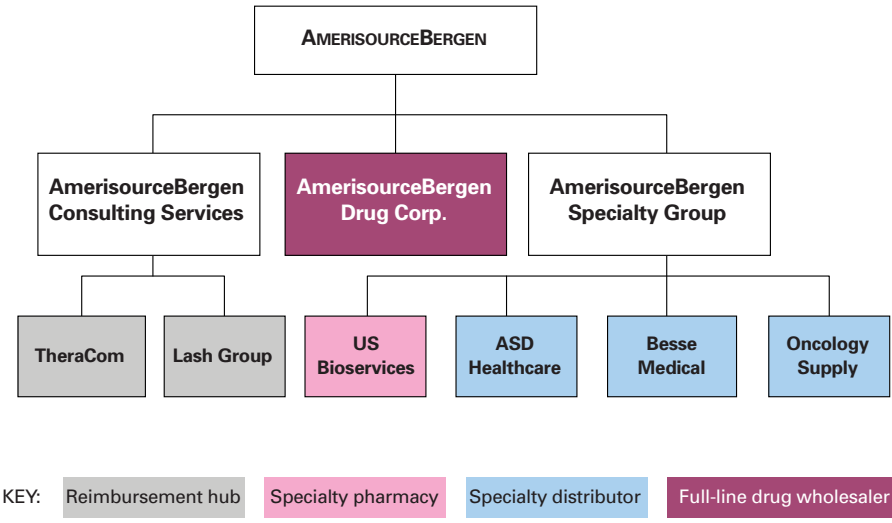
If there are kinks in specialty channels, they reflect continuous motion at both ends. Consolidation among distributors has been in progress for three decades, starting with the full-line wholesalers and then extending to the specialty subsector. At the dispensing end, there is increasing fragmentation as retail pharmacies vie with other dispensers for a piece of the action.

To understand current specialty channels, it may help to place them in the context of modern drug distribution in general, starting with the wholesale trade.

Today, the three largest U.S. wholesalers are McKesson, Cardinal Health, and AmerisourceBergen Corp. (ABC). In 2011, estimated sales were $112 billion, $102 billion, and $80 billion, respectively, according to Fein. Two of these companies, ABC and McKesson, also dominate the specialty wholesale segment. Fein estimates that three ABC subsidiaries and one McKesson subsidiary account for 75 percent of specialty product distribution revenue in the United States (Fein 2011).

About 30 years ago, pharmaceuti-

FIGURE 4
AmerisourceBergen subsidiaries involved in distribution channels for specialty drugs



AmerisourceBergen is divided into three operating segments, each of which is involved in some aspect of the distribution of specialty pharmaceuticals. Not depicted are ABC's business operations in consulting (Xcenda) and packaging.

Source: Biotechnology Healthcare Analysis 2012

cal wholesaling became a business in which it was difficult to succeed without really trying; that is, merely tweaking some legacy distribution model was insufficient. Fein says there wasn't a single factor behind the massive reconfiguration of drug wholesaling at the end of the 20th century but rather a set of complementary innovations. During the era of consolidation, *trying* meant the simultaneous application of multiple solutions to the challenges presented by pharmaceutical distribution. Some innovations were processes that reduced costs, such as more efficient procedures for retrieving products from warehouses. Others were services that added value, such as electronic ordering systems that reduced a pharmacist's time needed to place an order.

In 1978, 147 drug wholesalers shared a U.S. distribution market worth $4.9 billion. By 1995, the number of wholesalers had been reduced to 53. Fein sets 1978 as the start of the consolidation spurt because that's when the forerunner of AmeriSource, the diversified conglomerate known as Alco Standard, entered drug wholesaling via the acquisition of a Philadelphia-based regional distributor. It proved to be a voracious consolidator. By the time it went public in 1995 as AmeriSource, the corporation had bought out 17 competitors. It consumed still more up to its 2001 merger with Bergen Brunswig, which itself had been an avid participant in consolidation.

McKesson & Robbins, which traces its origins to a company founded in 1833 to fill the medicine chests on clipper ships, became the first national drug wholesaler in 1929. The 1950s were boom times for retail drug stores and, by 1961, McKesson served 33,000 of them, along with 5,000 hospitals. Except for the acquisition in 1995 of FoxMeyer Drug, McKesson essentially sat on the sidelines during the consolidation era.

In recent years, however, McKesson has emerged as the second-largest specialty distributor in the United States, creating McKesson Specialty in 2002. From that launch pad, McKesson expanded its specialty interest through the 2006 acquisition of a small GPO, National Oncology Alliance, followed by the 2007 acquisition of the Oncology Therapeutics Network (OTN)/Onmark, and US Oncology in 2010. As a result, McKesson Specialty has a 25 percent share of the U.S. specialty drug distribution market. Fein estimates that in fiscal 2011, McKesson Specialty generated $6.5 billion in sales, about 6 percent of the corporation's total sales (Fein 2011).

Easy as ABC

McKesson may have been the first drug wholesaler with nationwide reach and it may be the biggest wholesaler in terms of overall sales, but ABC is the largest player in specialty channels, with mutually reinforcing subsidiaries engaged in full-line wholesaling, specialty distribution, specialty pharmacy, and reimbursement hub services (Figure 4).

ABC distributes pharmaceuticals through AmerisourceBergen Drug

Corporation (ABDC) and subsidiaries in the AmerisourceBergen Specialty Group (ABSG). ABDC is a full-line wholesaler serving hospitals, clinics, independent and chain retail pharmacies, mail order pharmacies, and more. ABSG deals primarily with physicians, notably oncologists, through its specialty distributors, ASD Healthcare, Besse Medical, and Oncology Supply. ABC also owns a nationwide specialty pharmacy, US Bioservices, though it does not rank among the largest. In late 2011, ABC acquired the reimbursement hub TheraCom from CVS Caremark, adding it to its existing hub, the Lash Group, which Fein believes is the nation's largest hub provider.

By themselves, the three ABC subsidiaries engaged in specialty distribution account for half of the specialty distribution market (Fein 2011). Together with other ABSG subsidiaries, the specialty distributors generated $16 billion in sales during fiscal 2011, or 20 percent of ABC's estimated revenue (Fein 2011). Between 2004 and 2011, ABSG grew by 227 percent, Fein says, making it the fasting-growing ABC business group.

Whether such growth can be sustained is another question. For one thing, sales of anemia-related drugs have been declining because of safety concerns and Medicare payment issues, and ABSG is by far the largest distributor of Amgen products, including epoetin alfa (Epogen) and darbepoetin alfa (Aranesp) (Fein 2011). For another, McKesson's acquisition of US Oncology in late 2010 meant the loss of an $800 million logistics contract by a member of ABC's Specialty Group. The acquisition, according to Fein, makes McKesson a more formidable competitor.

"ABC has been the leader in the specialty distribution business for years," Fein says, "but in the past five years McKesson has built a powerful business in oncology group purchasing and specialty distribution."

Specialty and retail pharmacy

At the dispensing end, specialty and retail pharmacies gave customers $39 billion worth of prescriptions for specialty pharmaceuticals in 2010 (Fein 2012). In contrast to specialty distributors, which sell products to physicians and pharmacies, specialty pharmacies dispense products directly to patients. The top three companies in this sector, CVS Caremark, Accredo (owned by Medco Health Solutions), and CuraScript Specialty Pharmacy (SP) (owned by Express Scripts), all are owned by PBMs.

These PBMs have been busy sculpting their business lines to profit from the specialty pharmacy boom. To take one example, Express Scripts acquired CuraScript SP in 2004. The next year, Express Scripts acquired Priority Healthcare, then one of the largest biopharmaceutical and pharmacy distributors, and combined it with CuraScript. Its corporate home is within Express Scripts' HealthBridge Pharma & Biotech group, which also includes specialty distributor CuraScript SD and niche specialty pharmacy Freedom Fertility. HealthBridge also provides hub services. With this range of services, Express Scripts aspires to provide manufacturers with everything they need to move product to patients. In April, Express Scripts received FTC approval to complete its $29 billion acquisition of Medco.

The fourth-largest specialty pharmacy, Walgreens Specialty Pharmacy, gained its position through the acquisition of several regional and niche specialty pharmacies beginning in 2005 and continuing through today; a pending acquisition, BioScrip's community specialty pharmacy business — which serves mostly HIV, oncology, and transplant patients — was still awaiting regulatory approval in April.

Beyond the big three plus Walgreens and BioScrip, about a third of all revenue generated by specialty drug dispensing is still divided among smaller players owned by health plans, home healthcare providers, retail pharmacy chains, and smaller PBMs.

"Despite the size of the largest companies," says Fein, "there still is room for vigorous competition in this sector."

Next Issue: *Part 2 examines the future of specialty distribution channels: biosimilars, buy and bill, ePedigrees, the struggle among pharmacies to earn or retain a seat at the dispensing end — and why these factors are important to the commercial or Medicare payer or a self-insured employer.*

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